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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		10569583
	Filing Date		2006-02-23
	First Named Inventor	Neil Gallagher	
	Art Unit	1654	
	Examiner Name	Julie Ha	
	Attorney Docket Number	101213-1P US	

## U.S. PATENTS

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JH	1	5464853		1995-11-07	Chan, Ming F. et al.	
JH	2	5514691		1996-05-07	Chan, Ming F. et al.	
JH	3	5843902		1998-12-01	Garnick, Marc B. et al.	
JH	4	5763429		1998-06-09	Bishop, Charles W. et al.	
JH	5	4100274		1978-07-11	Dutta, Anand Swaroop, et al.	
JH	6	4767628		1988-08-30	Hutchinson, Francis G.	

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JH	1	20020055457	A1	2002-05-09	Janus, Todd J. et al.	
JH	2	20050014769	A1	2005-01-20	Osswald, Mathias et al.	
JH	3	20030092757	A1	2003-05-15	Singh, Amitabh et al.	

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JH	1	0682016	EP	A1	1995-11-15	Zeneca Ltd.		<input type="checkbox"/>
JH	2	0749964	EP	A1	1996-12-27	Zeneca Ltd.		<input type="checkbox"/>
JH	3	0510526	EP	A1	1992-10-28	F. Hoffmann-La Roche & Co.		<input checked="" type="checkbox"/>
JH	4	0526708	EP	A1	1993-02-10	F. Hoffman-La Roche AG		<input checked="" type="checkbox"/>
JH	5	0558258	EP	A1	1993-09-01	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>
JH	6	0569193	EP	A1	1993-11-10	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>

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JH	7	0640596	EP	A1	1995-03-01	Bristol-Myers Squibb Co.		<input type="checkbox"/>
JH	8	1424080	EP	A1	2004-06-02	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
JH	9	1256344	EP	A1	2002-11-13	Yamanouchi Pharmaceutical Co., Ltd.		<input type="checkbox"/>
JH	10	2295616	GB	A	1996-06-05	Zeneca Ltd.		<input type="checkbox"/>
JH	11	1995/26957	WO	A1	1995-10-12	Zeneca Ltd.		<input type="checkbox"/>
JH	12	1996/40681	WO	A1	1996-12-19	Zeneca Ltd.		<input type="checkbox"/>
JH	13	1998/40332	WO	A1	1998-09-17	Zeneca Ltd.		<input type="checkbox"/>
JH	14	2004/018044	WO	A2	2004-03-04	AstraZeneca AB		<input type="checkbox"/>
JH	15	2004/032922	WO	A1	2004-04-22	AstraZeneca AB		<input type="checkbox"/>
JH	16	2004/035057	WO	A1	2004-04-29	AstraZeneca AB		<input type="checkbox"/>
JH	17	2005/080403	WO	A2	2005-09-01	AstraZeneca AB		<input type="checkbox"/>

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JH	18	2006/056760	WO	A1	2006-06-01	AstraZeneca AB	<input type="checkbox"/>
JH	19	2001/00198	WO	A2	2001-01-04	California Institute of Technology	<input type="checkbox"/>
JH	20	2000/67024	WO	A1	2000-11-09	New York University	<input type="checkbox"/>
JH	21	2001/60370	WO	A1	2001-08-23	Yamanouchi Pharmaceutical Co. Ltd.	<input checked="" type="checkbox"/>
JH	22	1999/56761	WO	A1	1999-11-11	Davar, Gudarz	<input type="checkbox"/>
JH	23	2002/11713	WO	A2	2002-02-14	Abbott Laboratories	<input type="checkbox"/>
JH	24	2000/36918	WO	A1	2000-06-29	Marine Polymers Technologies, Inc.	<input type="checkbox"/>
JH	25	2002/085351	WO	A1	2002-10-31	Abbott Laboratories	<input type="checkbox"/>
JH	26	2002/49630	WO	A2	2002-06-27	Bristol-Myers Squibb Company	<input type="checkbox"/>
JH	27	1994/27979	WO	A1	1994-12-08	Immunopharmaceutics Inc.	<input type="checkbox"/>
JH	28	200191736	WO	A2	2001-12-06	Warner-Lambert Company	<input type="checkbox"/>

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JH	29	2001/44239	WO	A2	2001-06-21	Bristol-Myers Squibb Company	<input type="checkbox"/>
JH	30	2003/045434	WO	A2	2003-06-05	Board of Trustees of the University of Illinois	<input type="checkbox"/>
JH	31	2003/006041	WO	A1	2003-01-23	Takeda Chemical Industries, Ltd.	<input checked="" type="checkbox"/>
JH	32	2003/015820	WO	A1	2003-02-27	Takeda Chemical Industries, Ltd.	<input checked="" type="checkbox"/>
JH	33	1999/48530	WO	A1	1999-09-30	Merck & Co., Inc.	<input type="checkbox"/>
JH	34	2002/074034	WO	A2	2002-09-26	Boehringer Ingelheim Pharma KG	<input checked="" type="checkbox"/>
JH	35	2002/080960	WO	A2	2002-10-17	Medical Research Council	<input type="checkbox"/>
JH	36	2002/069906	WO	A2	2002-09-12	Cellegy Pharmaceuticals, Inc.	<input type="checkbox"/>
JH	37	2003/009805	WO	A2	2003-02-06	Brigham and Women's Hospital, Inc.	<input type="checkbox"/>
JH	38	2000/21509	WO	A2	2000-04-20	Imperial College Innovations Ltd.	<input type="checkbox"/>
JH	39	1996/09818	WO	A1	1996-04-04	Merck & Co., Inc.	<input type="checkbox"/>

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JH	40	2003/039539	WO	A2	2003-05-15	Merck Patent GMBH	<input checked="" type="checkbox"/>
JH	41	2005/063735	WO	A1	2005-07-14	Merck Patent GMBH	<input checked="" type="checkbox"/>
JH	42	0058481	EP	A1	1982-08-25	Imperial Chemical Industries PLC	<input type="checkbox"/>

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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
JH	1	MORRIS MICHAEL J ET AL: "Clinical approaches to osseous metastases in prostate cancer." The Oncologist, 2003, pages 161-173, vol. 8, no. 2	<input type="checkbox"/>
JH	2	ROSANO LAURA A ET AL: "Therapeutic targeting of the endothelin A receptor in human ovarian carcinoma," Cancer Research, 15 May 2003 (2003-05-15), pages 2447-2453, vol. 63, no. 10, XP002365689	<input type="checkbox"/>
JH	3	WALCZAK J R ET AL: "Pharmacological Treatments for Prostate Cancer," Expert Opinion on Investigational Drugs, 2002, pages 1737-1748, Vol . 11, no. 12, Ashley Publications, Ltd., London, GB, XP009008862	<input type="checkbox"/>
JH	4	ROSANO, LAURA ET AL, "ZD4054, a specific antagonist of the endothelin A receptor, inhibits tumor growth and enhances cytotoxicity of paclitaxel in human ovarian carcinoma in vitro and in vivo," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
JH	5	CURTIS, N. ET AL: "ZD4054 specifically inhibits endothelin A receptor-mediated anti-apoptotic effects, but not endothelin B receptor-mediated pro-apoptotic effects," September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland	<input type="checkbox"/>
JH	6	LIU, GLENN ET AL, "Tolerability profile of ZD4054 is consistent with the effects of endothelin A receptor-specific antagonism," May 13-17, 2005, ASCO Annual Meeting, Orlando, Florida	<input type="checkbox"/>

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JH	7	MORRIS, C. ET AL, "ZD4054: specificity for endothelin A receptor following single-dose administration in healthy volunteers," September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland	<input type="checkbox"/>
JH	8	DREICER, R. ET AL., "ZD4054 specifically inhibits endothelin A receptor-mediated effects but not endothelin B receptor-mediated effects," February 17-19, 2005, ASCO Prostate Cancer Symposium, Orlando, Florida	<input type="checkbox"/>
JH	9	TODD, MARTIN ET AL, "Metabolite Factories: Use of microbial systems to generate metabolites of an endothelin receptor antagonist," July 3-8, 2005, Biotrans 2005, Delft, The Netherlands	<input type="checkbox"/>
JH	10	MORRIS, CD ET AL. "Specific inhibition of the endothelin A receptor with ZD4054: clinical and preclinical evidence," British Journal of Cancer, 2005, 92, 2148-2152	<input type="checkbox"/>
JH	11	CURWEN, J.O., "ZD4054 : a specific endothelin A receptor antagonist with potential utility in prostate cancer and metastatic bone disease," European Journal of Cancer, November 2002 (2002-11), vol. 38, page S102, Pergamon Press, Oxford, GB, XP004403782	<input type="checkbox"/>
JH	12	CURTIS, N. ET AL, "ZD4054 blocks ET-1-stimulated phosphorylation of p44/42 mitogen-activated protein kinase and proliferation of osteoblast cells," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
JH	13	MORRIS, C.D. ET AL, "ZD4054 reduces endothelin-1-induced forearm vasoconstriction in healthy male volunteers," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
JH	14	ROSANO, LAURA, "Combined targeting of the endothelin receptor and the epidermal growth factor receptor in ovarian cancer shows enhanced antiproliferative effects," April 1-5, 2006, AACR 2006, Washington, DC	<input type="checkbox"/>
JH	15	CURWEN, J. ET AL., "ZD4054 : a specific endothelin A receptor antagonist with potential utility in prostate cancer and metastatic bone disease," 19-22 November 2002, EORTC-NCI-AACR, Frankfurt, Germany	<input type="checkbox"/>
JH	16	NELSON, JOEL B. ET AL., "Endothelin-1 Production and Decreased Endothelin B Receptor Expression in Advanced Prostate Cancer, Journal of Cancer Research, February 15, 1996, pages 663-668, Volume 56	<input type="checkbox"/>
JH	17	KROODSMA, J.M., ET AL., "Endothelinen: modelijk een nieuw farmacologisch aangrijpingspunt bij hartvaatziekten, nierziekten en oncologische aandoingen," Nederlands Tijdschrift Voor Geneeskunde, 1997, pages 1806-1810, Volume 141, Part 38	<input checked="" type="checkbox"/>

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JH	18	"Endothelin Inhibitors: Exploring Novel Therapeutics," Symposium, June 7-8, 1999, Washington, DC, Iddb Meeting Report, 25 June 1999	<input type="checkbox"/>
JH	19	BOVEN, E., "American Society of Clinical Oncology-35th Annual Meeting (Part 1), Symposium, May 15-18, 1999, Atlanta, GA, Iddb Meeting Report, 13 September 2001	<input type="checkbox"/>
JH	20	MCKINNON, C., "American Society of Clinical Oncology-35th Annual Meeting (Part 4), Symposium, May 15-18, 1999, Atlanta, GA, Iddb Meeting Report, 13 September 2001	<input type="checkbox"/>
JH	21	ADENIYI, A., "American Urological Association-94th Annual Meeting," Symposium, May 1-6, 1999, Dallas, TX, Iddb Meeting Report, 26 August 1999	<input type="checkbox"/>
JH	22	BOVEN, E., "American Society of Clinical Oncology-35th Annual Meeting, 15-18 May 1999, Atlanta, GA," ID Drugs, 1999, pages 617-619, Vol. 2, No. 7	<input type="checkbox"/>
JH	23	MCKINNON, C., "Topoisomerase inhibitors and other new agents," ID Drugs, 1999, pages 629-632, Vol. 2, No. 7	<input type="checkbox"/>
JH	24	ADENIYI, A., "American Urological Association-94th Annual Meeting May 1-6, 1999, Dallas, TX", ID Drugs, 1999, pages 656-658 Vol. 2, No. 7	<input type="checkbox"/>
JH	25	NELSON, JOEL B., "Editorial: Endothelin Receptor Antagonists in the Treatment of Prostate Cancer," The Prostate, pages 91-92, 2001, Volume 49	<input type="checkbox"/>
JH	26	NELSON, JOEL B., "The Role of the Endothelin Axis in Prostate Cancer," The Prostate Journal, pages 126-130, 1999, Volume 1, Number 3	<input type="checkbox"/>
JH	27	NELSON, JOEL B., "The Role of Endothelin-1 and Endothelin Receptor Antagonists in Prostate Cancer, British Journal of Urology, pages, 45-48, 2000, Volume 85, Suppl. 2	<input type="checkbox"/>
JH	28	NELSON, JOEL B., "Identification of endothelin-1 in the pathophysiology of metastatic adenocarcinoma of the prostate", Nature Medicine, pages 944-949, September 1995, Volume 1, No. 9	<input type="checkbox"/>



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JH	29	CARDUCCI, MICHAEL A., "Endothelin Receptor Antagonist, ABT-627, For Prostate Cancer: Initial Trial Results," The Journal of Urology, page 176, 1999, Volume 161(4) Suppl	<input type="checkbox"/>
JH	30	JARVIS, MICHAEL F., ET AL., "ABT-627, an endothelin ETA receptor-selective antagonist, attenuates tactile allodynia in a diabetic rat model of neuropathic pain," European Journal of Pharmacology, pages 29-35, 2000, Vol. 388. No. 1	<input type="checkbox"/>
JH	31	WILLIAMS, E.D., "The combination of a specific endothelin A receptor antagonist ZD4054 and submaximal bisphosphonate pamidronate prevents bone metastasis," Poster Session, Angiogenesis and metastasis inhibitors, 8 November 2006, European Journal of Cancer Supplements, page 15, Volume 4, No. 12, page 15.	<input type="checkbox"/>
JH	32	BAGNATO, ANNA, ET AL., "Autocrine Actions of Endothelin-1 as a Growth Factor in Human Ovarian Carcinoma Cells," Clinical Cancer Research, 1995, pages 1059-1066, Vol. 1.	<input type="checkbox"/>
JH	33	WU-WONG, JINSHYUN R., "Endothelin attenuates apoptosis in human smooth muscle cells," Biochemical Journal, pages 733-737, 1997, Vol. 328	<input type="checkbox"/>
JH	34	SPINELLA, FRANCESCA, ET AL., "Endothelin-1 Induces Vascular Endothelial Growth Factor by Increasing Hypoxia-inducible Factor-1a in Ovarian Carcinoma Cells," The Journal of Biological Chemistry, pages 27850-27855, August 2, 2002, Volume 277, No. 31	<input type="checkbox"/>

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#### EXAMINER SIGNATURE

Examiner Signature	/Julie Ha/	Date Considered	1/19/2007
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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### CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

### SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Lucy Padget/	Date (YYYY-MM-DD)	2007-01-19
Name/Print	Lucy Padget	Registration Number	L0074

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.